IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Tanzi *et al.*

Appl. No. *To be assigned*
(DIV of Appl. No. 09/148,503)

Filed: August 10, 2001

For: **An Alpha-2-Macroglobulin Diagnostic Test**

Confirmation No.: *To be assigned*

Art Unit: *To be assigned*

Examiner: *To be assigned*

Atty. Docket: 0609.4460004/JAG/HLK

Preliminary Amendment and Statement Under 37 C.F.R. § 1.63(d)(2) Deleting Inventor

Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination, kindly amend the above-captioned application as follows:

Amendment

In the Inventorship:

Please delete Bradley T. Hyman and George W. Rebeck from the inventive entity of the above-captioned application.

In the Title:

Please substitute the current Title with the following Title:

AN ALPHA-2-MACROGLOBULIN ISOTYPE DIAGNOSTIC TEST FOR ALZHEIMER'S DISEASE

In the Specification:

Please amend the specification as follows:

Please substitute the current version of paragraph [0001] with the following paragraph:

[0001] This application is a divisional of, and claims priority to, Application No. 09/148,503, filed on September 4, 1998. Application No. 09/148,503 claims priority to U.S. Provisional Application No. 60/057,655, filed on September 5, 1997, and U.S. Provisional Application No. 60/093,297, filed on July 17, 1998. The entire contents of each of these applications are herein incorporated by reference.

In the Claims:

Please amend the claims as follows:

Please cancel claims 1-32 without prejudice or disclaimer.

Please add the following claims:

33. (New) A method of assessing an individual's risk of developing AD comprising isotyping a blood tissue or cell sample taken from an individual, wherein said sample comprises α_2M, to determine whether said sample contains the α_2M-2 variant.

34. (New) The method of claim 33, further comprising drawing a conclusion regarding said individual's risk of developing Alzheimer's disease based on the existence of the α_2M-2 variant in said sample, wherein a finding that said sample contains said α_2M-2 isoform indicates that said individual is at risk for developing AD.

35. (New) The method of claim 33, further comprising isotyping said sample to determine whether said sample contains the α_2M-1 variant.

36. (New) The method of claim 33, wherein said sample is contacted with an antibody specific for said A2M-2 variant.

37. (New) The method of claim 35, wherein said sample is contacted with an antibody specific for said α_2M-1 variant.

38. (New) A method used to aid in the diagnosis of AD comprising isotyping a sample taken from an individual, wherein said sample comprises α_2M, to determine whether said sample contains the α_2M-2 variant.

39. (New) The method of claim 38, wherein said individual is suspected to have Alzheimer's disease.

40. (New) The method of claim 39, further comprising drawing a conclusion regarding the diagnosis of said individual based on the existence of the α_2M-2 variant in said sample, wherein a finding that said sample contains said α_2M-2 variant is an indicator that said individual has AD.

41. (New) The method of claim 38, further comprising isotyping said sample to determine whether said sample contains the α_2M-1 variant.

42. (New) The method of claim 38, wherein said sample is contacted with an antibody specific for said A2M-2 variant.

43. (New) The method of claim 38, wherein said sample is contacted with an antibody specific for said α_2M-1 variant.

Remarks and Statement Under 37 C.F.R. § 1.63(d)(2)

I. Status of the Claims

Prompt and favorable consideration of the Preliminary Amendment is respectfully requested. Claims 1-32 have been canceled and claims 33-43 have been added. Claims 33 and 38 are independent claims. Upon entry of the foregoing Preliminary Amendment, claims 33-43 will be subject to examination in the application. Applicants reserve the right to file one or more continuation applications directed to the subject matter of the canceled claims.

II. Support for the Amendment

As required under 37 C.F.R. § 1.63(d)(2), Applicants hereby request the deletion of Bradley T. Hyman and George W. Rebeck from the named inventive entity of the above-captioned application. This change in inventorship is necessitated by the above amendment deleting claims 1-4, 6-16, 18-23, 25, 27, 29 and 31 (which are among claims 1-32). As Bradley T. Hyman and George W. Rebeck are not inventors of the subject matter of any of the remaining claims, their deletion from the inventorship is believed proper. Accordingly, upon entry of this request, the inventive entity would be changed from Rudolph E. Tanzi, Bradley T. Hyman, George W. Rebeck and Deborah L. Blacker, to Rudolph E. Tanzi and Deborah L. Blacker.

Applicants have amended the Title to reflect the subject matter claimed and have amended the specification to cross-reference related Application No. 09/148,503.

In addition, new claims 33-43 have been added. Support for these claims can be found, *inter alia*, in paragraphs 15, 18, 38, and 52-57, and in original claims 19-27.

In parent Appl. No. 09/148,503, the Examiner made a restriction requirement in which the claims were divided into two groups. Group II included claims 19-27 and 30-32, and were drawn to methods of diagnosing Alzheimer's disease by isotyping α_2M. New claims 33-43 of

the present application are consonant with claims 19-27 in Group II of this restriction requirement.

These changes are believed to introduce no new matter, and their entry is respectfully requested.

Summary

Applicants believe that this application is now in condition for examination. Early notice to this effect is respectfully requested.

Respectfully submitted,

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Date August 10, 2001

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Version of Amendment With Markings to Show Changes Made

In the Title

AN ALPHA-2-MACROGLOBULIN ISOTYPE DIAGNOSTIC TEST FOR ALZHEIMER'S DISEASE

In the Specification:

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